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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/815,778	04/02/2004	Gordana Vunjak-Novakovic	X-9408	8172

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EXAMINER

SINGH, SATYENDRA K

ART UNIT	PAPER NUMBER
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1657

MAIL DATE	DELIVERY MODE
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10/09/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/815,778	Applicant(s) VUNJAK-NOVAKOVIC ET AL.	
	Examiner Satyendra K. Singh	Art Unit 1657	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

- A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.
- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
 - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
 - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 December 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-43 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-43 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

Applicant's response filed with the office on December 29th 2006 is duly acknowledged.

Applicants are advised that the Examiner of this application has been changed, and all further communications regarding this application should be directed to Examiner Satyendra K. Singh (Art Unit 1657).

Election/Restrictions

Applicant's election of group I (claims 1-38 with species of figures 3 and 4) in the reply filed on December 29th 2006 is acknowledged. Because applicant (though states that the election has been made with traverse; see remarks, line 1) did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

However, upon further considerations, further restriction of group I is required.

Election/Restrictions of group I

NOTE: claim 31 is missing (taken to be a typographical error) from the original claim listing presented by applicants. Accordingly, subsequent claims have been renumbered by this Examiner to be in proper claim format. Thus, elected group I (original claims 1-30 and 32-38) is now represented by claims 1-37, and the non-elected group II (original claims 39-44) is now represented by claims 38-43. In addition, renumbered claims 35-37 have now been taken as being dependent from claim 34 (instead of original claim 35 of group I). Applicants are requested to present appropriate amendments to the claims in response to this office action. *The instant claims are referred in this office action according to the new claim numbering (i.e. after claim 30) as discussed above, hereafter.*

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- 1a. Claims 1-12, drawn to a **cartilage repair assembly** comprising an allograft bone plug, and an allograft milled cartilage mixture in a

biocompatible carrier (as specifically recited in instant claim 1), classified in class 623, subclass 11.11 and various depending on the components.

- lb. Claims 13-23, drawn to a **cartilage repair assembly** comprising a sterile shaped structure dimensioned to fit in a drilled bore (as specifically recited in instant claim 13) in a cartilage defect area, and sterile milled cartilage pieces mixed in a carrier, classified in class 623, subclass 13.12, and various depending on the components.
- lc. Claim 24-33, drawn to a **cartilage repair assembly** comprising a sterile shaped structure dimensioned to fit in a drilled bore (as specifically recited in instant claim 24) and sterile milled cartilage pieces mixed in a bioabsorbable carrier, classified in class 623, subclass 20.14, various, depending on the components.
- ld. Claims 34-37, drawn to a **cartilage repair assembly kit** comprising a sterile shaped structure (as recited in instant claim 34) housed in a first sterile container, and milled allograft cartilage pieces mixed in a carrier housed in a second sterile container, said first and second sterile containers being packaged together, classified in class 623, subclass 548, and various depending on the components.

The inventions are distinct, each from the other because of the following reasons:

1. Inventions of groups (la-ld) are distinct from each other. The different inventions are directed to distinct products having distinct components that have distinct characteristics (i.e. structural and /or functional features), as claimed. The invention of

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groups (1a-1c) are directed to distinct cartilage repair assemblies, whereas the invention of group 1d is drawn to a cartilage repair assembly kit (see instant claim 34, in particular) having distinct structural components such as two "sterile containers" packaged together in a specific manner, which is not required by the inventions of groups (1a-1c). The inventions of groups 1a, 1b, and 1c are distinct from each other, as the invention of group 1b requires "sterile milled cartilage pieces" and "a sterile shaped structure" which is "dimensioned to fit" in a drilled bore "in a cartilage defect area so that said shaped bone and cartilage cap when centered in the bore does not engage the side wall of the bore in an interference fit" (see instant claim 13, in particular), which is not required by the inventions of group 1a and 1c. The invention of group 1c requires that the shaped structure be "dimensioned to fit" in a drilled bore in a cartilage defect such that "when centered in the bore can be rotated in said bore", which is not required by the inventions of groups 1a and 1b, as claimed. In addition, the invention of group 1a requires "an allograft bone plug" and "allograft milled cartilage mixture", the limitations that are not required by the inventions of groups 1b or 1c, as claimed. Similarly, the invention of group 1d does not require structural limitations of "interference fit" or centering and rotation test (as recited in instant claim 13 and 24, respectively) for the "shaped structure" as recited in the inventions of groups 1b and 1c.

Restriction for examination purposes as indicated is proper because all these inventions listed in this action are independent or distinct for the reasons given above and there would be a serious search and examination burden if restriction were not required because one or more of the following reasons apply:

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- (a) the inventions have acquired a separate status in the art in view of their different classification;
- (b) the inventions have acquired a separate status in the art due to their recognized divergent subject matter;
- (c) the inventions require a different field of search (for example, searching different classes/subclasses or electronic resources, or employing different search queries);
- (d) the prior art applicable to one invention would not likely be applicable to another invention;
- (e) the inventions are likely to raise different non-prior art issues under 35 U.S.C. 101 and/or 35 U.S.C. 112, first paragraph.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a invention to be examined even though the requirement may be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse. Traversal must be presented at the time of election in order to be considered timely. Failure to timely traverse the requirement will result in the loss of right to petition under 37 CFR 1.144. If claims are added after the election, applicant must indicate which of these claims are readable on the elected invention.

If claims are added after the election, applicant must indicate which of these claims are readable upon the elected invention.

Should applicant traverse on the ground that the inventions are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Species Election

This application contains claims directed to the following patentably distinct species as follows:

1. Claim 11 (the invention of group Ia) recites various "additives" in a Markush group: applicant is required to elect single specie for examination, if group Ia is elected.

growth factors, human allogenic cells, human autologous bone marrow cells, human allogenic bone marrow cells, stem cells, demineralized bone matrix, cartilage, and insulin.

2. Claim 18 (the invention of group Ib) recites various "additives" in a Markush group: applicant is required to elect single specie for examination, if group Ib is elected.

growth factors, human allogenic cells, human bone autologous marrow cells, human allogenic bone marrow cells, stem cells, demineralized bone matrix, cartilage, and insulin.

Claim 20 (the invention of group Ib) recites various "carrier" in a Markush group: applicant is required to elect single specie for examination, if group Ib is elected.

sodium hyaluronate, gelatin, collagen, chitosan, alginate, buffered PBS, Dextran or polymers.

3. Claim 31 (the invention of group Ic) recites various "additives" in a Markush group: applicant is required to elect single specie for examination, if group Ic is elected.

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growth factor, human allogenic cells, human bone marrow cells, human autologous bone marrow cells, demineralized bone matrix, cartilage, and insulin.

Claim 33 (the invention of group Ic) recites various "carrier" in a Markush group: applicant is required to elect single specie for examination, if group Ic is elected.

sodium hyaluronate, gelatin, collagen, chitosan, alginate, buffered PBS, Dextran or polymers.

4. Claim 36 (the invention of group Id) recites various "additives" in a Markush group: applicant is required to elect single specie for examination, if group Id is elected.

growth factors, human allogenic cells, human allogenic bone marrow cells, human autologous bone marrow cells, stem cells, demineralized bone matrix, cartilage, and insulin.

Claim 37 (the invention of group Id) recites various "carrier" in a Markush group: applicant is required to elect single specie for examination, if group Id is elected.

sodium hyaluronate, gelatin, collagen, chitosan, alginate, buffered PBS, Dextran or polymers.

The species are independent or distinct because claims to the different species recite the mutually exclusive characteristics of such species. In addition, these species are not obvious variants of each other based on the current record.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species (from each of the claims mentioned above) for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 1, 13, 24, and 34 are deemed generic.

There is an examination and search burden for these patentably distinct species due to their mutually exclusive characteristics. The species require a different field of search (e.g., searching different classes/subclasses or electronic resources, or

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employing different search queries); and/or the prior art applicable to one species would not likely be applicable to another species; and/or the species are likely to raise different non-prior art issues under 35 U.S.C. 101 and/or 35 U.S.C. 112, first paragraph.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species to be examined even though the requirement may be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

The election of the species may be made with or without traverse. To preserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the election of species requirement, the election shall be treated as an election without traverse. Traversal must be presented at the time of election in order to be considered timely. Failure to timely traverse the requirement will result in the loss of right to petition under 37 CFR 1.144. If claims are added after the election, applicant must indicate which of these claims are readable on the elected species.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the species unpatentable over the

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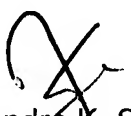
prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other species.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Satyendra K. Singh whose telephone number is 571-272-8790. The examiner can normally be reached on 9-5MF.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon P. Weber can be reached on 571-272-0925. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Satyendra K. Singh
Patent Examiner
Art Unit 1657



SANDRA E. SAUCIER
PRIMARY EXAMINER